



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,184	01/28/2005	John J.R. Mertens	1592 WO/US	8281

7590

01/18/2006

Mallinckrodt Inc  
675 McDonnell Boulevard  
PO Box 5840  
St Louis, MO 63134

EXAMINER

CHU, YONG LIANG

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/523,184

Applicant(s)

MERTENS, JOHN J.R.

Examiner

Yong Chu

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***DETAILED ACTION***

Claims 1-24 are currently pending in the instant application.

***Priority***

This application is a 371 of PCT/US03/24436, filed on 1 August 2003.

Acknowledgement is made of Applicant's claim for EP Patent Application (EPO)02078228.0 under 35 U.S.C. § 119(a-d), filed on 2 August 2002.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

***Lack of Unity Requirement***

Claims 1-24 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

**Group I:** Claims 1 (in part), 2, and 3 are drawn to halogenated amino acid analogues for

use in diagnosis, which compounds have the general formula

$$\text{X}-(\text{CH}_2)_n-\text{R}(\text{CH}_2)_m-\underset{\text{NH}_2}{\text{CH}}-\text{COOH},$$

wherein R is methyl, ethyl, phenyl, pyridyl, etc. If this group is elected, Applicant is requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

**Group II:** Claims 1 (in part), 4 (in part), 5, 8, 9, 10 (in part) and 11, are drawn to halogenated amino acid analogues as claimed in claim 1, wherein the halogen is radioactive selected from  $^{18}\text{F}$  and  $^{19}\text{F}$ , and a pharmaceutical composition comprising one or more claimed amino analogs and an recipient, carrier or diluent. If this group is

elected, Applicant is requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

**Group III:** Claims 1 (in part), 4 (in part), 6, and 10 (in part), are drawn to halogenated amino acid analogues as claimed in claim 1, wherein the halogen is radioactive selected from  $^{18}\text{F}$  and  $^{19}\text{F}$ , and a pharmaceutical composition comprising one or more claimed amino analogs and an recipient, carrier or diluent. If this group is elected, Applicant is requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

**Group IV:** Claim 12 is drawn to use of the amino acid analogues as claimed in claim 1 in preparation of a pharmaceutical composition.

**Group V:** Claims 13 and 15 are drawn to use of the amino acid analogues claimed in claim 1 or a composition claimed in claim 11 for use in diagnosis, wherein the diagnosis is performed by means of Positron Emission Tomography (PET) or functional Magnetic Resonance Imaging (MRI).

**Group VI:** Claim 14 is drawn to a method for diagnosing a patient for the presence of tumors and/or metastases, which comprises administration of a diagnostic effective amount of one or more of the amino acid analogues as claimed in claim 1, and visualizing the localization of the analogs in the patients' body.

**Group VII:** Claims 16-21 are drawn to precursor compounds for preparing radiolabeled amino acid analogues as claimed in claim 1. If this group is elected, Applicant is requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

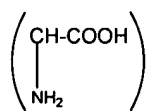
**Group VIII:** Claims 22-24 are drawn to a method for preparing the amino acid analogues as claimed in claim 1, comprising substitution of the leaving group with a radioactive halogen atoms.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) **Groups I-VIII** lack unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-VIII** is amino acid moiety of formula



. This technical feature is not a special technical feature, because it fails to define a contribution over the prior art of amino acid, such as glycine, which are very common chemicals and can be found in many reference books, such as Aldrich Catalog (see Aldrich Catalog 2005-2006 page 1280). Therefore, claims 1-24 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the

complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product, a process for the manufacture of said product, or a method of use.

Furthermore, with respect to **Groups I-VIII**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than one product, process, and method of use. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

**As a result, the claims lack unity of invention and applicant is required to elect a single invention.**

The claims directed to a single method of preparation and a single method of use will be examined along with the elected invention so long as it is commensurate in scope therewith.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

#### ***Telephone Inquiry***

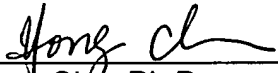
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

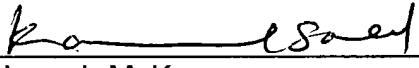
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Yong Chu, Ph.D.  
Patent Examiner, AU 1626

KAMALA A. SAEED, PH.D.  
PRIMARY EXAMINER  
  
for Joseph McKane  
Supervisory Patent Examiner  
AU 1626